JUL 1 3 2001

Reynolds Medical Ltd.
Special 510(k)
Lifecard CF 7-Day Holter Recorder

510(k) Summary

(1) Submitter Information

Name: Reynolds Medical Ltd.

Address:

1 Harforde Court
John Tate Court
Hertford, Herts SG13 7NW
ENGLAND

Telephone Number: 44-1992-507700

Contact Person:
Dr. George Myers (Official Correspondent)
Medsys Inc.
377 Route 17 S
Hasbrouck Heights, NJ 07604
Telephone 201-727-1703
Fax 201-727-1708

Date Prepared: June 8th, 2001

(2) Name of Device

Trade Name: Lifecard CF 7-Day Holter recorder
Common Name: Holter Recorder.
Classification name: Recorder, Magnetic Tape, Medical (please note that this device does not use magnetic tape)

(3) Equivalent legally-marketed device.

Reynolds Lifecard CF Holter recorder, K001025

(4) Description

The device is a portable Holter recorder designed to record the patient's ambulatory electrocardiogram for up to seven days (with the appropriate flashcard and battery). The

use of the modified device as described in its labeling has not changed. The fundamental science technology of the device has not changed.

The unit uses a data compression system to store seven days of ECG data in extended mode. In "standard" mode (up to two days of recording) the unit is identical to the predicate device.

(5) Intended Use

The Lifecard CF is a portable Holter recorder intended to record the patient's ambulatory electrocardiogram for up to seven days (with the appropriate flashcard and battery). The electrocardiograms can then be analyzed by Holter analyzers. The unit does no analysis.

(6) Performance Data

(a) Non-clinical tests

The Lifecard CF 7-Day Holter recorder meets the requirements of AAMI EC38, IEC 601-1 and IEC 601-1-2.

The software has undergone extensive validation testing. The compression algorithm has been separately tested.

(b) Clinical tests

None required.

(c) Conclusions

The Lifecard CF 7-Day Holter recorder is equivalent in safety and efficacy to the legally-marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 3 2001

Reynolds Medical, Ltd.
George H. Myers, Sc.D.
Designated Agent
c/o Medsys Inc.
377 Route 17 South
Hasbrouck Heights, NJ 07604

Re: K011837
Trade Name: LifeCard CF 7-day Holter Recorder
Regulation Number: 870.2800
Regulatory Class: II (Two)
Product Code: MWJ
Dated: June 7, 2001
Received: June 12, 2001

Dear Dr. Myers:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have

under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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510(k) Number (if known): K011837

Indications for Use Form

Device Name: Lifecard CF 7-Day Holter recorder

Indications for Use:

The Reynolds Lifecard CF 7-Day Holter recorder is a modification of the Reynolds Lifecard CF Holter Recorder, K001025. It is indicated when it is desired to record the patient's ambulatory electrocardiogram.

It is a portable Holter recorder designed to record the patient's ambulatory electrocardiogram for up to seven days.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the-Counter Use**
(Per 21 CFR 810.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011837